



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 11, 2000

MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 9480-T / Sani-Wipe
DP Barcode: D261695
Case No: 065184

To: Marshall Swindell, PM 33 / Tony Kish
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian D. Blackwell, M.S., Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Ian D. Blackwell

Through: Emily Mitchell, M.S., Acting Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Emily Mitchell 5/25/00

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: PDI

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
n-Akyl dimethyl benzyl ammonium chloride	0.0175
Isopropyl alcohol	6.93
<u>Other Ingredient(s):</u>	<u>93.06</u>
Total:	100.00%

Don't send these Reviews
To Regis that because
efficacy + chem don't
coincide w/ (EPA) TR.

T. Kish
8/15/00

BACKGROUND: PDI has submitted a set of six product efficacy studies in support of the registration of their product, Sani-Wipe. Sani-Wipe is a sanitizing towelette for use on food contact surfaces. The studies were conducted by MycoScience, Inc. The MRID Numbers are 449774-07 through 449774-12.

While the registration product is "Sani-Wipe", the test material used in these studies is identified as "Food Contact Surface Sanitizer". However, upon request, the registrant faxed a letter stating that "Food Contact Surface Sanitizer SR" is "Sani-Wipe". The registrant should be certain that all test materials are properly identified in the future.

RECOMMENDATIONS: PSB findings are:

1. MRID Number 449774-07: "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes for Use As a Sanitizer For Previously Cleaned Food-Contact Surfaces" by Richard E. Arsenault. MycoScience, Inc. Project Number 99-044NP. Study Completion Date 5/10/99.
2. MRID Number 449974-08: "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes For Use As a Sanitizer For Previously Cleaned Food-Contact Surfaces" by Richard E. Arsenault. MycoScience, Inc. Project Number 99-153NP. (This study is similar to 449774-07 except it tested a 60-day old test material sample.)
3. MRID Number 449774-09: "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes For Use As a Sanitizer for Previously Cleaned Food-Contact Surfaces" by Richard E. Arsenault. MycoScience, Inc. Project No. 99-186NP. Study Completion Date 6/10/99.
4. MRID Number 449774-10: "Nice-Pak Products, Inc. Efficacy of Single Use Impregnated Towelettes For Use As a Sanitizer For Inanimate Non-Food Contact Surfaces" by Richard E. Arsenault. MycoScience Labs, Inc. Project number 99-293NP. Study Completion Date 9/15/99.
5. MRID Number 449774-11: "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes For Use As A Sanitizer For Inanimate Non-Food Contact Surfaces" by Richard E. Arsenault. Mycoscience Labs, Inc. Project Number 99-318NP. Study Completion Date 10/1/99.
6. MRID Number 449774-12: "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes For Use As A Sanitizer for Inanimate Non-Food Contact Surfaces" by Richard E. Arnault. Mycoscience Labs, Inc. Project Number 99-183-NP. Study Completion Date 6/4/99.

The above listed studies are not acceptable because no data results were submitted for the expressed liquid subcultured from used towelettes. See efficacy data requirements for pre-saturated or impregnated towelettes for hard surface disinfection. If express liquid was subcultured, results must be submitted or efficacy of product must be retested.

LABELING:

Label review cannot be completed until efficacy requirements are fulfilled.